



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/954,646 | 09/18/2001 | Seth A. Foerster | END-777 | 8823 |

27777 7590 01/12/2005

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

MANTIS MERCADER, ELENI M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3737

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

98

Office Action Summary

Application No.

09/954,646

Applicant(s)

FOERSTER ET AL.

Examiner

Eleni Mantis Mercader

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-51, 54-62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-51, 54-62 and 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks , filed 10/16/2004, with respect to the double patenting rejections have been fully considered and are persuasive. The double patenting rejections has been withdrawn.

Applicant's arguments filed on 10/16/2004 have been fully considered but they are not persuasive with respect to the prior art rejections of record. The Examiner maintains that in the broadest reasonable interpretation the Campbell et al.'936 reference teaches all the elements as pointed out in the rejection. With respect to the 103 rejections, the Applicant is respectfully redirected to the rejection of record, which while it points out what Edwards does not teach, for example the use of a shaft, it introduces the teachings of other references such as Hirsch et al.'319, which does teach pushing the marker of interest at the area of interest and wherein the marker is fully inserted into the body, i.e. by using a shaft. For at least these reasons the rejections are maintained and made final.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

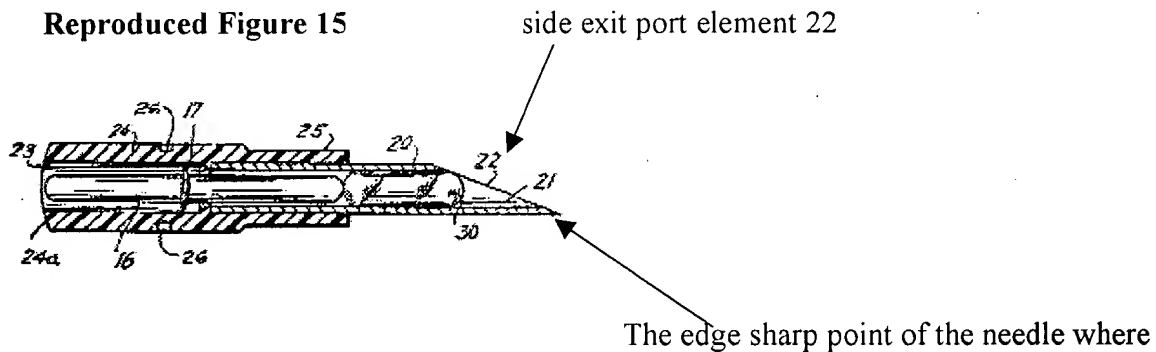
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 46 is rejected under 35 U.S.C. 102(e) as being anticipated by Campbell et al.'936.

Art Unit: 3737

Campbell et al.'936 teach an introducer for inserting a marker element into a particular tissue element having an introducer with a tube having a lumen an axial opening at the proximal end of the tube (see in Figure 10, plunger 18), a side exit port at the distal end of the port (see Figure 15 below, element 22) and a closed distal end (sharp point of the needle in Figure 15 is the closed distal end) with at least one discrete marker positioned in the tube (see Figure 18 showing a marker cartridge assembly for delivering markers at the area of interest) and a shaft extending from the axial opening and ejecting the marker from the side exit port by the application of compressive force (referring to the plunger 18 pushing the marker 30; see col. 4, lines 24-58) such that no marker element extends outside the body (referring to subcutaneous penetration; see col. 1, lines 33-43).



the arrow points is interpreted as the closed distal end.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

Art Unit: 3737

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 46-51, 54-62 and 65-67 rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al.'308 in view of Rank et al.'426, of record and Hirsch et al.'319.

Edwards et al.'308 teach all the elements of the current invention including a catheter including a closed distal end as indicated in Figure 2 or 12 or 18 for performing surgical biopsy (see col. 3, lines 46-65) with imaging capability (see col. 7, lines 50-62) and with multiple ports for introducing elements therethrough such as aspiration tubes (see for example element 1422 of Figure 18).

Edwards et al.'308 do not teach marking the tissue at the area of interest prior to its excision.

In the same field of endeavor, Rank et al.'426 teach marking the tissue at the area of interest such as breast tissue prior to its excision during biopsy while imaging with the imager of interest with a marker or multiple markers (see the abstract and see col. 5, lines 1-68 and col. 6, lines 1-15).

It would have been obvious to one skilled in the art at the time that the invention was made to have marked the tissue of interest as taught by Rank et al.'426 in the invention of Edwards et al.'308 during biopsy in order to mark and accurately localize the area of interest prior to the excision through biopsy (see in '426 col. 1, lines 10-47).

Edwards et al.'308 in view of Rank et al.'426 do not specifically teach a shaft for pushing the marker through the catheter/needle.

Art Unit: 3737

In the same field of endeavor, Hirsch et al.'319 teach pushing the marker of interest at the area of interest and wherein the marker is fully inserted into the body (see Figure 1, and col. 1, lines 50-68 and col. 2, lines 1-25).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Edwards et al.'308 in view of Rank et al.'426 and incorporated the teaching of Hirsch et al.'319 in order to mark the area of interest with a marker prior to the excision by pushing the marker through the catheter and by replacing for example the aspiration tube as indicated in Figure 18 of '308 with the shaft or mandrel as taught by '319 in order to push a marker therethrough as per the above stated teachings.

The material of the marker will be dependent on the imager of choice in order to be able to accurately localize the marker prior to excision.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 3737

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM